PAMELA WILLIAMSON

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

No. 15 Civ. 08725(GBD)

----------x

UMB Bank, N.A., as Trustee,

Plaintiff

vs.

SANOFI,

Defendant

----------x

VIDEOTAPED DEPOSITION OF PAMELA WILLIAMSON

Thursday, May 3, 2018 9:04 a.m.

Weil, Gotshal & Manges

100 Federal Street, Boston, MA

Reported by:

Janet Sambataro, RMR, CRR, CLR

JOB NO. 141488

itself is executed in a manner that is "controlled" and well executed and in accordance with GCP, good clinical practice.

The other is that there is a control arm in the protocol, a comparator arm. The control can be either a placebo, it can be an active drug, but it is what you measure or compare against.

Q. And in the context of a controlled clinical trial, the FDA looks to the sponsor to reduce bias in the trial; correct?

A. Yes.

Q. And when I say, "bias," you understand that bias can come from many different sources?

A. Yes.

Q. One bias, for example, might be in a clinical trial where there is a person rating the outcome of the trial on a subjective basis. They may know the patient is being treated with one drug, another drug or a placebo; correct?

A. Say the beginning part of your sentence again.

Q. I'll rephrase the question.

When a clinical trial has, as one of its endpoints, a review by a person who makes a

[redacted]

Q. Thank you.

And you don't just hope that the data shows support for your indication; correct? You actually plan a trial to get the data that you believe will support the FDA agreeing with you on your indication; correct?

MR. AMSEL: Objection to the form.

A. Well, you hope and you do your best to plan.

Q. But planning also includes developing a protocol for the trial, which has endpoints and statistical analyses that within the nature of the regulatory approval process will support an approval for that proposed indication; correct?

MR. AMSEL: Objection to form.

A. To the extent that it's possible to do so, yes.

Q. And your experience is that the individuals at Genzyme are competent

effects or identifying patients who may have enhanced efficiency -- efficacy, sorry, when the drug is given to them; correct?

A. If that -- if that potential exists, sure. It's part of the course of drug development and learning about your drug.

Q. Right. Because if you've got a diagnostic, then say well, then this patient benefits from it. That's a good thing to develop because it means you can identify the patients who will benefit from the drug?

A. If it's possible. Yes.

Q. I'll give you an example. If you have a diagnostic test for Huntington's --

A. Mm-hmm.

Q. -- you know who to give the Huntington drug to --

A. Mm-hmm.

Q. -- correct?

A. Yes.

Q. Okay. Do you have recollections of discussions at Genzyme about allocation of resources to biomarkers to help identify ways in which alemtuzumab could be either safer or more

effective in patient populations?

A. No.

Q. Would it surprise you if that work was done?

A. No.

Q. Because that is part of what a responsible pharmaceutical company does; correct?

A. If they can.

Q. Absolutely.

MR. AMSEL: Why don't we -- we've been going about an hour and a half or so. Why don't we take a -- take a break now.

MR. WEISS: Again, if you wish to take a break, that's entirely in your purview.

MR. AMSEL: Okay.

THE VIDEOGRAPHER: This is the end of Tape No. 2. Off the record, 12:08 p.m.

(Lunch recess was taken.)

THE VIDEOGRAPHER: This is the beginning of Tape No. 3. On the record, 12:49 p.m.

BY MR. WEISS:

Q. So, Ms. Williamson, I show you what has been previously marked as Exhibits 120, 121 and

[redacted]

Q. So we are definitely in sync. I was going to ask you about that next.

What is life cycle management?

A. I'm sorry. I was giving you an opportunity to find whatever you were looking for.

Q. No. I can actually multitask. It's a bad habit.

A. A life cycle management, in very general terms, is taking a look at a program or product or portfolio of products and taking a look at what you may be doing next, what -- how do you continue to learn about your product? How do you continue to expand the potential use of your product? How do you continue to educate on your product? It's about looking at your product or program through the life of its existence.

Q. And life cycle management, or LCM, is a natural part of what pharmaceutical companies do;

correct?

A. I assume most companies do.

Q. Well, based on your experience in the industry?

A. Yes. Yes.

Q. Sorry. You walked over me.

Based on your experience in the industry, prudent pharmaceutical companies analyze, and, if appropriate, engage in life cycle management?

A. Yes.

MR. AMSEL: Objection to the form.

Q. And life cycle management can include reformulation; correct?

A. It can include many things.

Q. But punch them out.

A. That could be one.

Q. It will be quicker. It can include reformulation?

A. It can include reformulation.

Q. For example, something Elan did a lot, going from an IR to an ER to an SR.

A. New formulations, different routes of administration, faster activity, any number of things depending upon what the product is.